UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS

SAN ANTONIO DIVISION

UNITED STATES OF AMERICA	§	
	§	
v.	§	
	§	
VASCULAR SOLUTIONS, INC.,	§	CRIMINAL NO. 5:14-CR-00926
	§	
and	§	
	§	
HOWARD C. ROOT	§	
	§	
Defendants.	§	

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE INDICTMENT OR, IN THE ALTERNATIVE, TO PRECLUDE THE GOVERNMENT FROM USING DEFENDANTS' TRUTHFUL SPEECH TO PROVE MISBRANDING AND ADULTERATION COUNTS

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INTRODUCTION

The First Amendment to the United States Constitution prevents the government from punishing citizens for truthful speech. Yet with this indictment, the government seeks to prosecute the defendants, Vascular Solutions and its CEO, Howard Root, for Vascular Solutions' sales representatives speaking truthfully to doctors about a medical device that it was lawful to sell and lawful for doctors to use to treat their patients.

In the government's view, the freedom of speech does not apply to speech about the "off-label" use of a medical device — *i.e.*, the lawful use by doctors of a medical device that the Food and Drug Administration has authorized for sale, for a particular use that FDA has not itself authorized. But the two courts that have considered the government's theory, the Second Circuit in *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012), and the Southern District of New York in *Amarin Pharma, Inc. v. FDA*, No. 15-cv-03588, 2015 WL 4720039 (S.D.N.Y. Aug. 7, 2015), squarely rejected it. Addressing the theory that so-called "off-label promotion" is a basis for criminal prosecution, the *Caronia* court held that the First Amendment precluded the prosecution of a sales representative for off-label but truthful speech about an otherwise lawfully marketed product. The court reasoned that even if FDA approves a product to treat only illness A, doctors are free to use the product — and companies are free to speak truthfully about the use of the product — to treat illness B. The court held that "criminaliz[ing] the simple promotion of a drug's off-label use by pharmaceutical manufacturers and their representatives . . . would run afoul of the First Amendment." 703 F.3d at 162. The court accordingly "construe[d] the misbranding provisions of the [Food, Drug and Cosmetic Act ("FDCA")] as not prohibiting and criminalizing the truthful off-label promotion of FDA-approved prescription drugs." *Id.* at 168. As a result, "the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug." *Id.* at 169. Last week, the *Amarin* court followed

suit, rejecting the government's effort to limit *Caronia* to its facts and holding that "Amarin [a pharmaceutical manufacturer] may engage in truthful and non-misleading speech promoting the off-label use of [Amarin's drug] . . . and[,] under *Caronia*, such speech may not form the basis of a prosecution for misbranding." *Amarin*, 2015 WL 4720039, at *36. No court has held otherwise.

The *Caronia* and *Amarin* decisions were compelled by a long line of the Supreme Court's First Amendment decisions, including *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011). There, the Court struck down a state statute that burdened promotional speech by pharmaceutical manufacturers. The Court in *Sorrell* reasoned that "[s]peech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment." *Id.* at 2659. It pointed out that the statute at issue "disfavor[ed] marketing, that is, speech with a particular content," *id.* at 2663, and that "[i]n its practical operation" the law went "even beyond mere content discrimination, to actual viewpoint discrimination." *Id.* (internal quotation marks omitted).

The charged promotion in this case relates to a medical device used to treat varicose veins called the Vari-Lase® Endovenous Laser Procedure Kit. Doctors regularly use laser ablation to treat several varicose veins in the legs, including the most-commonly treated saphenous veins that run up the leg and the less-commonly treated perforator veins that connect the saphenous veins to deeper veins in the leg. No one disputes that doctors may legally use the Vari-Lase system to treat all of these veins. In fact, Congress in the FDCA explicitly prohibited FDA from interfering with doctors' practice of medicine. *See* 21 U.S.C. § 396. But the government takes the position that the authorization Vascular Solutions received from FDA to sell its Vari-Lase products applies only to their use to treat certain varicose veins (saphenous veins) and not others (perforator veins). According to the government, that means that Vascular Solutions is prohibited from speaking truthfully to doctors about the use of the device to treat perforator veins, even though doctors are entirely free to use the device to treat perforator veins.

Caronia and *Amarin* rejected the government's theory, which prohibits off-label promotion and thereby punishes truthful speech. As the Second Circuit explained, the government's off-label promotion theory is improperly content-based because it disfavors particular messages, "distinguish[ing] between favored speech and disfavored speech on the basis of the ideas or views expressed." *Caronia*, 703 F.3d at 165 (internal quotation marks omitted). The government's theory also facially discriminates by "target[ing] one kind of speaker" (*id.*) — pharmaceutical and device manufacturers — as no doctor, scientist, researcher, or anyone else in the world could be prosecuted for speaking truthfully about an off-label use. The government's off-label promotion theory thus violates the principles of content- and viewpoint-neutrality that lie at the core of the First Amendment.

Furthermore, as the Second Circuit concluded, the method the government has chosen — muzzling manufacturers' truthful speech about lawful uses of their products — does not directly advance its asserted interests. If off-label use itself were prohibited, perhaps the government could justify prohibiting speech about off-label use. But far from being prohibited, off-label use is accepted and often essential to patient care. As the Second Circuit aptly put it, the "government's construction of the FDCA essentially legalizes the outcome — off-label use — but prohibits the free flow of information that would inform that outcome." *Id.* at 167. The government's notion that doctors must be shielded from truthful, non-misleading speech is anathema to the public interest as well as the First Amendment. "[I]n the fields of medicine and public health, 'where information can save lives,' it only furthers the public interest to ensure that decisions about the use of prescription drugs, including off-label usage, are intelligent and well-informed." *Id.* (quoting *Sorrell*, 131 S. Ct. at 2664, 2671).

The Second Circuit also held that the speech-based criminal prohibition chosen by the government restricts far more protected speech than necessary to achieve the government's asserted

interests. "Numerous, less speech-restrictive alternatives are available, as are non-criminal penalties." *Id.* Instead of silencing device manufacturers, the government could impose disclosure requirements on manufacturers to ensure that doctors understand that the regulated speech concerns a use not approved by FDA. Indeed, so far as the First Amendment is concerned, the government could limit off-label use itself or even prohibit it altogether. "If the First Amendment means anything, it means that regulating speech must be a last — not first — resort." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002). Yet when it comes to off-label use, targeting speech "seems to have been the first strategy the Government thought to try." *Id.* *Sorrell* and *Caronia* compel the conclusion that the First Amendment prevents the government from punishing Vascular Solutions or Mr. Root based on truthful speech.

Perhaps the best evidence that the government understands that the Second Circuit gutted its theory of prosecution is the nature of the prosecution of Glen Holden, a related case before this Court. The government contends that Mr. Holden engaged in off-label promotion in Connecticut (in the Second Circuit) and falsely denied his off-label promotion to a grand jury in this District. One would have expected the government to join Mr. Holden along with the company and Mr. Root in this indictment, since Mr. Holden allegedly engaged in the off-label promotion included in the conspiracy charge. Yet the government charged Mr. Holden only with making false statements and conspicuously did not charge him with the underlying off-label promotion. There was every reason to join Mr. Holden in this indictment, but one compelling reason not to: His acts occurred in Connecticut where the government knows that off-label promotion is constitutionally protected under *Caronia*.

Ignoring its loss in *Caronia* — a loss the government opted not to ask the Second Circuit to rehear en banc or the Supreme Court to review — the government sought this indictment using the same rejected theory that truthful promotion is a basis for prosecution. Although the government

has refused to disclose its legal instructions to the grand jury (the defendants are moving to compel production of those instructions), it is clear from the materials the defendants do possess that the prosecutors did not instruct the grand jury consistent with *Caronia*. To the contrary, the prosecutors emphasized alleged off-label promotion that occurred in Connecticut and New York, as if *Caronia* did not exist. And when a grand juror asked whether "honest" promotion was different from "dishonest" promotion, the prosecutors did not tell the grand jury about *Caronia* or the First Amendment; instead, they continued asking lay witnesses leading questions that presumed that honest promotion was equally prohibited. The prosecutors went so far as to tell the grand jury that it was "unlawful to *use* the Vari-Lase equipment on perforators, period" (Exhibit 1, USA-00008471-72 (emphasis added)) — a statement that is plainly incorrect and that not even the government has defended.

The government's erroneous comments and instructions to the grand jury raise a grave doubt about the validity of the indictment. Although the indictment also alleges misleading promotion, there is no way to know whether the grand jury improperly relied on truthful speech in returning the indictment. And there is every reason to believe that it did: the government did not even present evidence to the grand jury that the vast majority of the alleged statements were false or misleading, nor does it do so in the indictment. The indictment should therefore be dismissed. In the alternative, the defendants ask for an order *in limine*, based on *Sorrell* and *Caronia*, precluding the government from relying on truthful speech to prove its charges.

BACKGROUND

I. Vascular Solutions

Founded in 1997, Vascular Solutions is a medical device company that has invented, developed, and launched over 100 new medical devices used to diagnose and treat a variety of vascular medical conditions. Defendant Howard Root is Vascular Solutions' co-founder and has

been its Chief Executive Officer since inception. Indictment ¶ 2. One of Vascular Solutions' more than 100 medical devices is the Vari-Lase system, which is used by physicians to deliver laser energy in the treatment of varicose veins. *Id.* ¶ 11.

The Vari-Lase system uses "heat to shut varicose veins permanently, allowing the body to recruit healthier veins to move the blood." *Id.* This is a minimally invasive, one-hour procedure usually performed in a physician's office where the patient walks in before treatment and walks out afterwards. In essence, the physician inserts a sheath into the varicosed vein, slips a glass fiber connected to a laser energy generator into the sheath, and transmits laser energy through the fiber and into the vein while slowly pulling the fiber and sheath through the vein to close the length of the varicose vein.

This matter involves the use of one version of a Vari-Lase procedure kit to treat a particular kind of varicose vein called a perforator vein. The legs have two major vein networks: the deep and the superficial venous systems. The deep veins are closer to the bones, while the superficial veins, primarily the saphenous veins, are closer to the skin. Veins connecting the two systems are called perforator veins. *Id.* ¶ 13.

FDA authorized Vascular Solutions to market the Vari-Lase system and procedure kits "'for the treatment of varicose veins and varicosities associated with superficial reflux of the Great Saphenous Vein, and for the treatment of incompetence and reflux of superficial veins in the lower extremity.'" *Id.* ¶ 12. Around 2007, Vascular Solutions developed the Short Kit, a shorter version of its Vari-Lase procedure kit that was specifically designed for the treatment of short vein segments. *Id.* ¶ 17. The Short Kit is one of over 90 different configurations of the Vari-Lase procedure kits Vascular Solutions has sold. During the seven years the Short Kit was on the market, sales represented just 0.1% of Vascular Solutions' total U.S. sales. Over two-thirds of Vascular Solutions

sales representatives never sold even a single Short Kit for any clinical use. The government does not claim that the use of the Short Kit harmed any patients.

Doctors used the Short Kit to treat short segments of saphenous veins and to treat perforator veins. Interpreting the language of FDA's authorization, the government takes the position that "[t]he Vari-Lase devices were cleared for marketing by the FDA solely for treatment of superficial veins and the Great Saphenous Vein." *Id.* ¶ 12. The government thus believes that treatment of perforator veins is off-label and seeks to prosecute the defendants because Vascular Solutions sales representatives allegedly spoke to doctors about the use of the Vari-Lase system to treat perforator veins.[1]

II. The Indictment

In 2011, the government began investigating Vascular Solutions, and a grand jury returned an indictment of both defendants on November 13, 2014. The government's off-label promotion theory is featured in each of the nine counts. Counts Two through Nine are misbranding and adulteration counts, which allege that the defendants promoted the product for an off-label use for which it had received no FDA approval, no FDA clearance, and had inadequate directions for use in the product's labeling. *See* 21 U.S.C. § 351(f)(1)(B) (devices lacked FDA approval for off-label use); *id.* § 352(o) (defendants failed to submit a new request for FDA authorization for off-label use); *id.* § 352(f)(1) (device's labeling lacked adequate directions for off-label use). Count One charges a conspiracy to commit these substantive offenses.[2]

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[1] At trial we will show that treating perforator veins was encompassed within FDA's authorization and therefore was not "off-label" at all. As it must at this stage, this motion assumes the truth of the indictment's allegation that treating perforator veins was an off-label use, and explains why the defendants' truthful speech about that lawful, if off-label, use was nonetheless protected by the First Amendment.

[2] Count One, the hybrid misdemeanor/conspiracy count, alleges a three-pronged conspiracy. The first two prongs are misdemeanors: conspiracies to commit the adulteration and misbranding

Each charge is based on FDA's so-called "intended use" regulation. The government's theory is that the defendants' speech about the use of the Vari-Lase system to treat perforator veins created a new "intended use" for the product and that the defendants failed to obtain appropriate supplemental FDA marketing authorization for that new intended use. FDA defines "intended use" to refer to "the objective intent of the persons legally responsible for the labeling of devices." 21 C.F.R. § 801.4. The regulation makes clear that the manufacturer's *speech*, even if entirely truthful, may create a new intended use: "The intent is determined by such persons' *expressions* or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by *labeling claims, advertising matter, or oral or written statements* by such persons or their representatives." *Id.* (emphasis added).

The defendants' speech about the use of the Vari-Lase system to treat perforator veins, and the new "intended use" that speech allegedly created, is the basis for all of the government's charges. For example, the government relies on a sales representative's alleged dissemination of a document entitled "Tips for Treating Perforator Veins" (Indictment ¶ 43), communications detailing the differences between the Vari-Lase system and competing products (*id.* ¶ 41), and general encouragement to doctors to use the Vari-Lase system to treat perforator veins (*id.* ¶ 46). The indictment does not suggest that anything about this speech was false or misleading; instead, it reflects the government's insistence, in the teeth of *Caronia*, that the First Amendment is irrelevant.

Given that view and the way the government framed the indictment, it is no surprise that the government did not distinguish between truthful and allegedly misleading speech in presenting evidence to the grand jury or in instructing it on the law. Far from informing the grand jury that the

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offenses described above. The last prong charges a felony conspiracy to "defraud the United States and its agencies by concealing the[] sale of medical devices for unapproved use on perforator veins in order to impair and defeat the lawful function of the FDA and other law enforcement agencies." Indictment ¶ 33(c).

First Amendment prohibits criminalizing truthful speech, the prosecutors relied heavily on truthful speech and told the grand jury that off-label promotion is prohibited whether truthful or not. For example, the prosecutors asserted that "if you're being honest and tell the doctor the truth about it not being approved, you're still selling it for unapproved perforator use which is illegal, right?" (Exhibit 2, USA-00008328-29). And when a grand juror asked the prosecutors explicitly whether "the law makes a distinction between if you're selling it on honestly or dishonestly as a salesperson if you know it's off-label" (Exhibit 3, USA-00008379-81), the government did not tell the grand jury about *Caronia* or the First Amendment. Instead, the government elicited testimony (of lay witnesses) that — contrary to *Caronia* — all off-label promotion is prohibited. *See, e.g.*, *id.* ("So, based on your understanding, regardless of whether you tell the doctor it's unapproved or not, you still can't try to sell the unapproved use, right?").

To be sure, the indictment also alleges that the defendants engaged in false and misleading promotion — for example, about the availability of reimbursement and the results of a clinical trial. *See, e.g.*, *id.* ¶¶ 47-49. The defendants deny these allegations, but that does not matter for purposes of this motion, which asks the Court to dismiss the indictment because the government relied on truthful speech and failed to instruct the grand jury, even in response to a direct question on this issue, that it could not indict the defendants on the basis of truthful speech. In the alternative, the Court should issue an order that the government cannot rely on truthful speech to prove its charges.

ARGUMENT

The First Amendment provides that "Congress shall make no law . . . abridging the freedom of speech." U.S. Const. amend. I. The government's off-label promotion theory violates that bedrock limit on government power. The government seeks to hold Vascular Solutions and its founder criminally liable for speaking about a so-called off-label use of one of its medical devices, even though that use is entirely lawful and even though anyone other than the defendants may say

the same words without fear of criminal liability. What is more, the government seeks to punish the defendants for speech that is truthful and non-misleading. This interference with the free flow of truthful information between manufacturers and doctors cannot be reconciled with the First Amendment.

That is precisely what the Second Circuit held in *Caronia*. There, the government alleged that Caronia (a sales representative) marketed a drug for purposes FDA had not approved and that his off-label promotion rendered the drug misbranded. 703 F.3d at 157.[3] Before trial, Caronia moved to dismiss the indictment on the ground "that the application of the FDCA's misbranding provisions to his off-label promotional statements unconstitutionally restricted his right to free speech under the First Amendment." *Id.* at 158. The district court denied Caronia's motion, and a jury convicted him. The Second Circuit reversed. Relying on the Supreme Court's admonition that the First Amendment protects the "beneficial speech of pharmaceutical marketing" and that "in the fields of medicine and public health . . . information can save lives," *Sorrell*, 131 S. Ct. at 2664, 2670, the Second Circuit concluded that the government's interpretation of the FDCA to impose criminal liability based on truthful speech about lawful uses of a lawful product violated the First Amendment. It accordingly "construe[d] the misbranding provisions of the FDCA as not prohibiting and criminalizing the truthful off-label promotion of FDA-approved prescription drugs." 703 F.3d at 168.

Last week, the Southern District of New York followed *Caronia* and held that a manufacturer has the First Amendment right to engage in truthful, non-misleading promotional speech about off-label use of its FDA-approved drug. There, "Amarin sought relief confirming that, free from the

[3] Although *Caronia* involved the statutory and regulatory scheme governing drugs, the scheme governing medical devices is the same in all relevant respects. In particular, FDA's "intended use" regulations are materially identical in the drug and device contexts. *Compare* 21 C.F.R. § 201.128 (drugs) *with* 21 C.F.R. § 801.4 (devices).

threat of a misbranding action, it may engage in truthful and non-misleading speech with doctors intended to promote [its drug] for off-label use, and that its right to engage in such speech includes the right to initiate discussions on that subject and to engage in a dialogue with doctors about it." *Amarin*, 2015 WL 4720039, at *13. The government took the position that "*Caronia* . . . did not block the FDA from using speech as evidence of a manufacturer's intent in a prosecution for misbranding." *Id.* at *17. As the *Amarin* court explained, the government "views *Caronia* as a fact-bound decision that turned on the particular jury instructions and government jury addresses given in Caronia's trial." *Id.* at *22. But the court took the "considered and firm view . . . that, under *Caronia*, the FDA may *not* bring such an action based on truthful promotional speech alone, consistent with the First Amendment. A fair reading of that decision refutes the FDA's view that the Second Circuit's ruling was limited to the facts of Caronia's particular case." *Id.* at *23. That was so because "the reasons the Circuit gave in *Caronia* for that holding apply across-the-board to *all* truthful and nonmisleading promotional speech." *Id.* at *26 (emphasis in original). Accordingly, "[w]here the speech at issue consists of truthful and non-misleading speech promoting the off-label use of an FDA-approved drug, such speech, under *Caronia*, *cannot* be the act upon which an action for misbranding is based." *Id.* at *25 (emphasis in original).

I. The Government's Off-Label Promotion Theory Violates the First Amendment.

A. The Government's Off-Label Promotion Theory is Subject to Heightened Scrutiny Because It Discriminates On the Basis of Content and the Identity of the Speaker.

"The First Amendment requires heightened scrutiny whenever the government creates 'a regulation of speech because of disagreement with the message it conveys.'" *Sorrell*, 131 S. Ct. at 2664 (quoting *Ward v. Rock Against Racism*, 491 U.S. 781, 791 (1989)). "There is no question that 'the First Amendment means that government has no power to restrict expression because of its message, its ideas, its subject matter, or its content . . . . The essence of this forbidden censorship is

content control.'" *Muir v. Ala. Educ. Television Comm'n*, 688 F.2d 1033, 1043 (5th Cir. 1982) (en banc) (quoting *Police Dep't of Chi. v. Mosley*, 408 U.S. 92, 95 (1972)). *See also Ashcroft v. ACLU*, 535 U.S. 564, 573 (2002) ("[A]s a general matter, the First Amendment means that government has no power to restrict expression because of its message, its ideas, its subject matter, or its content.") (internal quotation marks omitted).

"The principle of viewpoint neutrality . . . underlies the First Amendment itself." *Bose Corp. v. Consumers Union of U.S., Inc.*, 466 U.S. 485, 505 (1984). The First Amendment "presumptively places" viewpoint discrimination "beyond the power of the government" because of "the specter that the government may effectively drive certain ideas or viewpoints from the marketplace." *Simon & Schuster, Inc. v. Members of N.Y. State Crime Victims Bd.*, 502 U.S. 105, 116 (1991). Accordingly, "[l]aws designed or intended to suppress or restrict the expression of specific speakers contradict basic First Amendment principles." *United States v. Playboy Entm't Grp., Inc.*, 529 U.S. 803, 812 (2000). As the Supreme Court recently emphasized, "[a] law that is content[-]based on its face is subject to strict scrutiny regardless of the government's benign motive, content-neutral justification, or lack of animus toward the ideas contained in the regulated speech." *Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2228 (2015) (internal quotation marks omitted). Such laws are "presumptively unconstitutional and may be justified only if the government proves that they are narrowly tailored to serve compelling state interests." *Id.* at 2226.[4]

[4] Nothing in *Reed* suggests that its holding that "strict scrutiny" applies to content-based burdens on protected speech somehow excludes commercial speech. *Reed* thus may go farther than *Sorrell*, which applied "heightened scrutiny" to a content-based burden on commercial speech. *See* 131 S. Ct. at 2664, 135 S. Ct. at 2226; *see also Caronia*, 703 F.3d at 165 (expressly following *Sorrell* and applying heightened scrutiny). Because it is clear that the government's off-label promotion theory cannot survive the heightened scrutiny applied in *Sorrell* and *Caronia* — or even review under the *Central Hudson* standard discussed in the next section — the Court does not need to decide whether strict, rather than heightened, scrutiny applies here or how strict scrutiny may differ from the heightened scrutiny applied in *Sorrell* and *Caronia*.

The government's interpretation of the FDCA's adulteration and misbranding provisions to prohibit off-label promotion "is content-based because it distinguishes between 'favored speech' and 'disfavored speech on the basis of the ideas or views expressed.'" *Caronia*, 703 F.3d at 165 (quoting *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 643 (1994)). Under the government's approach, "speech about the government-approved use of [devices] is permitted, while certain speech about the off-label use of [devices] — that is, uses not approved by the government — is prohibited, even though the off-label use itself is not." *Id.* Content- and viewpoint-based discrimination is the whole point of the government's ban on off-label promotion. The government's construction of the FDCA, moreover, is *speaker*-based "because it targets one kind of speaker — [device] manufacturers — while allowing others to speak without restriction." *Id.* As the Second Circuit explained, "the government's application of the FDCA permits physicians and academics, for example, to speak about off-label use without consequence, while the same speech is prohibited when delivered by [device] manufacturers." *Id.* That parallels the scheme the Supreme Court struck down in *Sorrell*, where "pharmaceutical companies were barred from obtaining and using prescriber-identifying information for marketing purposes, but a wide range of other speakers, including private and academic researchers, could acquire and use the information." *Id.*

As in *Caronia* and *Sorrell*, the government's position here "'has the effect of preventing [device manufacturers] — and only [device manufacturers] — from communicating with physicians in an effective and informative manner.'" *Id.* (quoting *Sorrell*, 131 S. Ct. at 2663). Indeed, "a claim to First Amendment protection here is more compelling than in *Sorrell* because this case involves a criminal regulatory scheme subject to more careful scrutiny." *Id.* "In the ordinary case it is all but dispositive to conclude that a law is content-based and, in practice, viewpoint-discriminatory," *Sorrell*, 131 S. Ct. at 2667, and there is no reason to depart from that rule here.

B. The Government's Off-Label Promotion Theory Cannot Survive Scrutiny Under *Central Hudson*.

Even if the government's off-label promotion theory did not trigger heightened scrutiny, it would run afoul of the First Amendment under the *Central Hudson* standard sometimes applied to restrictions on commercial speech. *See Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980). Both *Sorrell* and *Caronia* held first that heightened scrutiny applied, as explained in the previous section, and then went on to analyze the speech restrictions under *Central Hudson* as a fallback before holding that the restrictions violated the First Amendment under either analytical framework. *See Sorrell*, 131 S. Ct. at 2667; *Caronia*, 703 F.3d at 164. *Caronia*'s analysis is directly applicable here, and the Court should hold that the government may not prosecute the defendants based on truthful speech about the use of the Vari-Lase system to treat perforator veins regardless of whether the Court considers the issue under heightened scrutiny or *Central Hudson*.

"Commercial speech is no exception" to the First Amendment. *Sorrell*, 131 S. Ct. at 2664. "It is a matter of public interest that [economic] decisions, in the aggregate, be intelligent and well-informed. To this end, the free flow of commercial information is indispensable." *W. States Med. Ctr.*, 535 U.S. at 366 (alteration in original) (quoting *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 765 (1976)). "[A] . . . 'consumer's interest in the free flow of commercial information . . . may be as keen, if not keener by far, than his interest in the day's most urgent political debate.'" *W. States Med. Ctr.*, 535 U.S. at 366-67 (quoting *Va. State Bd. of Pharmacy*, 425 U.S. at 763). "That reality has great relevance in the fields of medicine and public health, where information can save lives." *Sorrell*, 131 S. Ct. at 2664. For that reason, "[s]peech in aid of pharmaceutical marketing . . . is a form of expression protected by the . . . First Amendment." *Id.* at 2659. *See also Amarin*, 2015 WL 4720039, at *24 (same).

"[N]on-content-based regulation and regulation of commercial speech — expression solely related to the economic interests of the speaker and its audience — are subject to intermediate

scrutiny" under *Central Hudson*. *Caronia*, 703 F.3d at 163. Under *Central Hudson*, unless the speech is "misleading" or "related to unlawful activity," it is presumptively protected and the burden is on the government to "assert a substantial interest to be achieved by restrictions on commercial speech," *Central Hudson*, 447 U.S. at 564, and to show that the regulation "directly advance[s] the governmental interest asserted" and is "not . . . more extensive than necessary to serve that interest." *Caronia*, 703 F.3d at 164. *See also Pub. Citizen Inc. v. La. Att'y Disciplinary Bd.*, 632 F.3d 212, 218 (5th Cir. 2011). "Criminal regulatory schemes . . . warrant even more careful scrutiny." *Caronia*, 703 F.3d at 163. The government, as "[t]he party seeking to uphold a restriction on commercial speech[,] carries the burden of justifying it," and "its burden is a 'heavy' one . . . that cannot be satisfied 'by mere speculation or conjecture.'" *Pub. Citizen Inc.*, 632 F.3d at 218 (citing *Bolger v. Youngs Drug Prods. Corp*, 463 U.S. 60, 71 n.20 (1983); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 516 (1996); and *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993)).

1. The Government's Off-Label Promotion Theory Does Not "Directly Advance" A Substantial Government Interest.

The government's scheme fails under *Central Hudson* because it does not directly advance a substantial government interest. First, as the government acknowledges, "[t]he FDCA does not prohibit doctors, in the exercise of medical judgment, from using medical devices for unapproved uses not included in the FDA-approved labeling." Indictment ¶ 6. "[O]ff-label [device] usage is not unlawful, and the FDA's [device] approval process generally contemplates that approved [devices] will be used in off-label ways." *Caronia*, 703 F.3d at 166. The Supreme Court has recognized that "'off-label' usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001). And FDA agrees that "off-label uses or treatment regimens may be important and may even constitute a medically recognized standard of care."

FDA, Guidance for Industry, *Good Reprint Practices for the Distribution of Medical Journal Articles* (Jan. 2009) ("Good Reprint Practices")[5].

Yet the government prohibits manufacturers from communicating truthful information about those same uses. This makes no sense. "As off-label [device] use itself is not prohibited, it does not follow that prohibiting the truthful promotion of off-label [device] usage by a particular class of speakers would directly further the government's goals of preserving the efficacy and integrity of the FDA's [device] approval process and reducing patient exposure to unsafe and ineffective [devices]." *Caronia*, 703 F.3d at 166. *See also Sorrell*, 131 S. Ct. at 2668-69; *Greater New Orleans Broad. Ass'n, Inc. v. United States*, 527 U.S. 173, 190 (1999) (the government's position is "so pierced by exemptions and inconsistencies that the Government cannot hope to exonerate it"). "Central to this litigation," therefore, "is that what a manufacturer may lawfully claim that a [device] does under the statutory and regulatory scheme, and what a physician may [use] a [device] for, do not match." *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 55 (D.D.C. 1998), *vacated on other grounds sub nom. by Wash. Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000). *See also Amarin*, 2015 WL 4720039, at *24 ("Construing the FDCA to prohibit truthful off-label promotion, the Circuit held, does not directly advance the asserted government interests — because off-label use of approved drugs is lawful, because the FDA's drug approval process itself contemplates such off-label use, and because prohibiting the truthful promotion of off-label drug usage by a particular class of speakers would not directly enhance the FDA's approval process or reduce patient exposure to unsafe and ineffective drugs.") (internal quotation marks omitted).

Second, the government's suppression of truthful speech about off-label uses is unconstitutionally paternalistic. The government may not justify suppressing speech based on the

[5] *Available at* http://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm.

"paternalistic assumption that the public will use truthful, nonmisleading commercial information unwisely." *44 Liquormart*, 517 U.S. at 497. "[B]ans against truthful, nonmisleading commercial speech . . . usually rest solely on the offensive assumption that the public will respond 'irrationally' to the truth. . . . The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good." *Id.* at 503. "It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us." *Va. State Bd. of Pharmacy*, 425 U.S. at 770. *See also Pub. Citizen Inc.*, 632 F.3d at 222.

Worse, the government prohibits manufacturers from speaking about off-label uses of their devices even with *doctors* — highly-trained and educated experts whom the government cannot plausibly claim need to be kept in the dark for their own good. "In making prescribing decisions, doctors want (and need) to know first and foremost if the [device] is the most safe and effective means to treat the conditions suffered by the patients." *Wash. Legal Found.*, 13 F. Supp. 2d at 63. *See also id.* ("[D]espite the FDA's occasional statements in its briefs to the contrary, physicians are a highly educated, professionally-trained and sophisticated audience."). The government's off-label promotion theory is a poster child for why paternalism is not a legitimate government interest when it comes to restricting speech: "[P]rohibiting off-label promotion by a [device] manufacturer while simultaneously allowing off-label use 'paternalistically' interferes with the ability of physicians and patients to receive potentially relevant treatment information; such barriers to information about off-label use could inhibit, to the public's detriment, informed and intelligent treatment decisions." *Caronia*, 703 F.3d at 166. "To the extent that the FDA is endeavoring to keep information from physicians out of concern that they will misuse that information, the regulation is wholly and completely unsupportable." *Wash. Legal Found.*, 13 F. Supp. 2d at 69.

In short, off-label use is perfectly lawful, and yet the government prohibits manufacturers from talking about it. The "government's construction of the FDCA essentially legalizes the outcome — off-label use — but prohibits the free flow of information that would inform that outcome." *Caronia*, 703 F.3d at 167. That is certainly not a direct way of achieving the government's avowed interests. "If the government's objective is to shepherd physicians to [use devices] only on-label, criminalizing manufacturer promotion of off-label use while permitting others to promote such use to physicians is an indirect and questionably effective means to achieve that goal." *Id.*

2. The Government's Theory Restricts Far More Speech Than Necessary To Serve Its Interest.

Moreover, the government's off-label promotion theory fails *Central Hudson*'s last requirement because the government has much less draconian means at its disposal. "[T]he government's construction of the FDCA to impose a complete and criminal ban on off-label promotion by [device] manufacturers is more extensive than necessary to achieve the government's substantial interests." *Caronia*, 703 F.3d at 167. "Numerous, less speech-restrictive alternatives are available, as are non-criminal penalties." *Id.* *See also Amarin*, 2015 WL 4720039, at *25 (same).

The government could, for example, engage in counter-speech. "If the government is concerned that off-label promotion may mislead physicians, it could guide physicians and patients in differentiating between misleading and false promotion, exaggerations and embellishments, and truthful or non-misleading information." *Caronia*, 703 F.3d at 168. *See also Sorrell*, 131 S. Ct. at 2671 ("Vermont may be displeased that detailers who use prescriber-identifying information are effective in promoting brand-name drugs. The State can express that view through its own speech."). The government could also "remind physicians and manufacturers of . . . the legal liability surrounding off-label promotion and treatment decisions." *Caronia*, 703 F.3d at 168. The government may worry that its speech would be less persuasive than that of device manufacturers. But the

government's "failure to persuade does not allow it to hamstring the opposition." *Sorrell*, 131 S. Ct. at 2671.

Apart from engaging in its own speech, the government could adopt a variety of less speech-restrictive regulations applicable to manufacturers. It could, for example, "develop . . . warning or disclaimer systems" to ensure that physicians understand that a use being discussed is off-label and its safety and effectiveness have not been reviewed by FDA. *Caronia*, 703 F.3d at 168. It could protect against misleading off-label promotion by requiring manufacturers to disclose any relevant negative information as well. And perhaps most obviously, the government could pursue its objectives through regulatory avenues rather than the hammer of criminal prosecution. "[T]he power of the state to prosecute and punish an individual for his or her conduct" is "one of the most awesome powers delegated to government in a free society." *In re The Herald Co.*, 734 F.2d 93, 105 (2d Cir. 1984). Where a civil remedy could also address the government's interest, criminalizing speech is "more extensive than is necessary to serve [the government's] interest." *Central Hudson*, 447 U.S. at 566.

The government has also asserted an interest in encouraging manufacturers to seek supplemental FDA authorizations for new uses. But the government does not need to sacrifice the First Amendment on the altar of that interest; manufacturers value the ability to tell doctors that a treatment has been approved by FDA and thus already have a strong incentive to seek supplemental authorizations. Preventing manufacturers from speaking about off-label uses while those uses are lawful, moreover, is at best an indirect and unnecessarily speech-restrictive way of encouraging such supplemental submissions. The government could directly require manufacturers to present off-label uses to FDA for review when a use reaches a certain level of prevalence — instead of silencing manufacturers' free speech about off-label uses in the hope that that will lead manufacturers to decide to present such uses to FDA. And, so far as the First Amendment is concerned, the

government could much more strongly "encourage" manufacturers to seek supplemental FDA authorizations for new uses by limiting or even prohibiting off-label use (across the board, or with respect to devices or uses that the government believes pose a greater risk).

The government's failure to define in any clear or binding way what speech will subject manufacturers to prosecution highlights the lack of narrow tailoring. "The vagueness of [a content-based regulation of speech] raises special First Amendment concerns because of its obvious chilling effect." *Reno v. ACLU*, 521 U.S. 844, 871–72 (1997). "[R]egulated parties should know what is required of them so they may act accordingly . . . precision and guidance are necessary so that those enforcing the law do not act in an arbitrary or discriminatory way. . . . When speech is involved, rigorous adherence to those requirements is necessary to ensure that ambiguity does not chill protected speech." *FCC v. Fox Television Stations, Inc.*, 132 S. Ct. 2307, 2317 (2012). The chilling effect arises because "'[v]ague laws force potential speakers to 'steer far wider of the unlawful zone' . . . than if the boundaries of the forbidden areas were clearly marked.'" *Brown v. Entm't Merchs. Ass'n*, 131 S. Ct. 2729, 2743 (2011) (quoting *Baggett v. Bullitt*, 377 U.S. 360, 372 (1964)).

When a law imposes criminal punishment, vagueness concerns are even graver. "The prohibition of vagueness in criminal statutes is a well-recognized requirement, consonant alike with ordinary notions of fair play and the settled rules of law, and a statute that flouts it violates the first essential of due process." *Johnson v. United States*, 135 S. Ct. 2551, 2556-57 (2015) (internal quotation marks omitted). "[P]roblems of vagueness" are "particularly treacherous where, as here, the violation of [a law's] terms carries criminal penalties and fear of incurring those sanctions may deter those who seek to exercise protected First Amendment rights." *Buckley v. Valeo*, 424 U.S. 1, 76-77 (1976) (per curiam) (footnote omitted). "The severity of criminal sanctions may well cause speakers to remain silent rather than communicate even arguably unlawful words, ideas, and images." *Reno*, 521 U.S. at 872.

FDA's "intended use[]" regulation targets speech with a sledgehammer instead of a scalpel. Under that regulation, any and all "expressions" and "oral or written statements" about an off-label use can render that use a new "intended use." *See* 21 C.F.R. § 801.4. And because a manufacturer by definition has not obtained FDA approval or supplemental FDA authorization to market a device for a use that is *off*-label, merely having an off-label "intended use" subjects the manufacturer to prosecution for misbranding or adulteration.

Perhaps recognizing that such a comprehensive prohibition on speech about off-label uses is the opposite of the narrow tailoring required by the First Amendment, FDA has sought to reassure manufacturers that the prohibition applies only to "promotional" speech. No statute or regulation, however, even uses that term, let alone defines it with the "precision" that would be "necessary to ensure that ambiguity does not chill protected speech." *Fox Television Stations, Inc.*, 132 S. Ct. at 2317. Like the line between "advocacy" and "discussion" at issue in *Buckley*, the distinction between "promotional" and "non-promotional" speech "may often dissolve in practical application." 424 U.S. at 42. And rather than amend its regulation to provide greater clarity in a legally binding manner, FDA has addressed this important First Amendment and fair-notice issue only in a series of "draft guidances" that are explicitly non-final and non-binding.[6]

[6] *See* Good Reprint Practices (stating that FDA does not plan to consider a manufacturer's distribution under certain circumstances of certain kinds of scientific and medical journals relating to an off-label use as creating a new intended use); FDA, Draft Guidance for Industry, *Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices* (Dec. 2011), *available at* http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm285145.pdf (stating that FDA does not plan to consider a manufacturer's private response to an unsolicited inquiry concerning an off-label use under certain circumstances as creating a new intended use); FDA, Revised Draft Guidance for Industry, *Distributing Scientific and Medical Publications on Unapproved New Uses — Recommended Practices* (Feb. 2014), *available at* http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm387652.pdf.

Those draft guidances provide cold comfort. They warn on their face that they do "not create or confer any rights," do "not operate to bind FDA" — let alone the Department of Justice — and simply "represent[] [FDA's] current thinking on this topic." *See, e.g.*, Good Reprint Practices. Nor do they clearly explain, even on their own non-binding terms, what constitutes impermissible "promotion" under FDA's "current thinking." Most recently, when Amarin sought legal clarity by filing a declaratory judgment action making the same basic First Amendment arguments as the defendants are making here, the government sought (unsuccessfully) to avoid judicial scrutiny of its off-label promotion theory by sending Amarin a letter stating that FDA did not intend to take action against Amarin if it made certain statements about an off-label use under certain circumstances in certain ways. *See* Letter from FDA to Amarin Pharma, *Amarin Pharma, Inc., et al. v. FDA*, No. 15-03588 (S.D.N.Y. June 5, 2015), ECF No. 53-1. But "the due process protection against vague regulations does not leave regulated parties at the mercy of *noblesse oblige*," *Fox Television Stations, Inc.*, 132 S. Ct. at 2318 (internal quotation marks omitted), and the unconstitutionally broad chilling effect imposed by the text of the intended use regulation thus remains. *See Citizens United v. FEC*, 558 U.S. 310, 324 (2010) (explaining that the government may not rescue an unconstitutional law or regulation "by carving out a limited exemption through an amorphous regulatory interpretation").[7]

To satisfy its burden under *Central Hudson*, the government must show that there is no "less restrictive alternative" to achieve its interests. *W. States Med. Ctr.*, 535 U.S. at 376. "[I]f the

[7] If FDA sought to ameliorate the broad chill its intended-use regulation imposes on truthful speech about off-label uses by amending its regulation (or promulgating a new regulation) after notice-and-comment rulemaking, the resulting regulation would carry the force of law and would be subject to challenge under the Administrative Procedure Act ("APA") as contrary to the First Amendment or the FDCA or as arbitrary and capricious. *See* 5 U.S.C. § 706. Perhaps for that reason, FDA has chosen to address this issue only in non-final, non-binding "guidances" that, as such, are not subject to judicial challenge under the APA. As a result, it falls to courts in the rare criminal prosecutions like *Caronia* and this case where the defendants stand up to defend their rights, rather than give in to government pressure to settle, to decide what limits the First Amendment places on the government's off-label promotion theory.

Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so." *Id.* at 371. Indeed, "[i]f the First Amendment means anything, it means that regulating speech must be a last — not first — resort. Yet here it seems to have been the first strategy the Government thought to try." *Id.* at 373.

C. The Government Cannot Evade the First Amendment By Claiming to Use Speech Merely as Evidence of Intent.

The government cannot make the serious First Amendment problems raised by its off-label promotion theory disappear by claiming that it is not attempting to punish speech directly but rather is merely considering the defendants' speech as "evidence" of a product's intended use. *See Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993) (holding that the "First Amendment . . . does not prohibit the evidentiary use of speech to establish the elements of a crime or to prove motive or intent").

First, rare is the law that openly and explicitly punishes speech. Even if the government's scheme does not directly *prohibit* speech in so many words, it certainly *burdens* it. "The Court has recognized that the distinction between laws burdening and laws banning speech is but a matter of degree and that the Government's content-based burdens must satisfy the same rigorous scrutiny as its content-based bans." *Sorrell*, 131 S. Ct. at 2664 (internal quotation marks omitted). And the Court has not hesitated to invalidate government actions that impose such burdens. For example, in *Minneapolis Star & Tribune Co. v. Minnesota Commissioner of Revenue*, the Court struck down an ink tax, reasoning that although the tax did not directly prohibit speech, "[a] tax that . . . targets individual publications within the press . . . places a heavy burden on the State to justify its action." 460 U.S. 575, 592-93 (1983). Similarly, in *Simon & Schuster, Inc. v. Members of the New York State Crimes Victims Board*, the Court invalidated a "Son of Sam" law that required "an accused or convicted criminal's income from works describing his crime" to be given to the victims of the crime, even though the law did not prohibit anyone from creating such works. 502 U.S. at 108. *See also Ark. Writers' Project, Inc. v. Ragland*, 481 U.S. 221, 229-30 (1987) (invalidating a sales tax on certain publications). Here,

the FDCA and FDA's intended-use regulation at the very least impose similar impermissible content-based burdens on manufacturers' truthful speech.

If the government could avoid First Amendment scrutiny by affixing the label "intent" to a content-based regulation interpreting a content-based statutory prohibition, the *Mitchell* exception would swallow the First Amendment rule. Congress cannot, for example, prohibit a seller of prescription drugs from advertising its prices. *Va. State Bd. of Pharmacy*, 425 U.S. at 773. But under the government's view, it could achieve exactly the same result — without so much as implicating the First Amendment — if an FDA regulation interpreted the ban as prohibiting the sale of prescription drugs with the "objective intent" that their price be publicly known, with the "objective intent" being demonstrated by the content of the seller's advertisements. In short, "the activities at issue in this case are only 'conduct' to the extent that moving one's lips is 'conduct,' or to the extent that affixing a stamp[,] and distributing information through the mails is 'conduct.'" *Wash. Legal Found.*, 13 F. Supp. 2d at 59.

What is more, unlike in *Mitchell*, the speech here *is* the crime. As the *Amarin* court explained in rejecting the government's argument on this point, "the proposition that speech can be admissible in evidence to prove intent or motive in a criminal case is beside the point here. Amarin's lawsuit is directed instead to the act requirement — the situation in which a misbranding action takes aim at truthful, non-misleading speech." *Amarin*, 2015 WL 4720039, at *26 (footnote omitted). Despite its name, FDA's "intended use" regulation does not require proof of a manufacturer's *subjective* intent, the familiar concept at issue in *Mitchell*. *See* Black's Law Dictionary 825 (8th ed. 2004) ("intent" means a party's "state of mind"). Instead, FDA bases "intended use" on the manufacturer's "*objective* intent," 21 C.F.R. § 801.4 (emphasis added), a novel and oxymoronic concept that is "unique to FDA law" and has "no direct parallels in either tort law or criminal law." Gregory Gentry, *Criminalizing Knowledge: The Perverse Implications of the Intended Use Regulations for Off-Label Promotion*

Prosecutions, 64 Food & Drug L.J. 441, 443 (2009). Under FDA's regulation, a manufacturer's speech promoting an off-label use is not *evidence* of a person's subjective intent; the promotion, rather, constitutes the objective intent that creates a new intended use of the device, no matter what the manufacturer subjectively intended.

Finally, *Mitchell* cannot help the government here because the underlying conduct in that case was a crime (battery) without regard to the defendant's speech, and the defendant's speech was relevant only because it justified a sentence for aggravated battery — it showed that the defendant had committed a non-speech-based crime with a particular mens rea. *Mitchell*, 508 U.S. at 489. Here, by contrast, the government is trying to impose criminal liability on the basis of the defendants' truthful speech about conduct that is entirely lawful (off-label use of a medical device). It was lawful for the defendants to sell the Vari-Lase system, having obtained FDA's authorization to do so. It was lawful for doctors to use the Vari-Lase system to treat perforator veins, even under the government's view that treating perforator veins is off-label. And it is the defendants' speech about that lawful conduct that, according to the government, somehow transforms their lawful conduct into a crime. The notion that the crimes of which the defendants stand accused are not speech-based cannot withstand scrutiny.

II. The Court Should Dismiss The Indictment Or, In The Alternative, Preclude the Government From Relying On Truthful Speech.

This Court should dismiss the indictment because the government relied on truthful speech in seeking the indictment and led the grand jury to believe, incorrectly, that the First Amendment permits prosecuting the defendants based on truthful speech. "[W]here a prosecutor's legal instruction to the grand jury seriously misstates the applicable law [(as opposed to simply failing to give legal instructions),] the indictment is subject to dismissal if the misstatement casts 'grave doubt that the decision to indict was free from the substantial influence' of the erroneous instruction." *United States v. Stevens*, 771 F. Supp. 2d 556, 566-67 (D. Md. 2011) (citing *Bank of Nova Scotia v. United*

States, 487 U.S. 250, 256 (1988)). When a grand juror asks a question about a critical legal issue, the prosecutor's "fail[ure] to tell the grand jury" about the law can "amount[] to prosecutorial error." *United States v. Cerullo*, No. 05-cr-1190 2007 WL 2462111, at *3 (C.D. Cal. Aug. 28, 2007) (unreported). Although "[t]he prosecutor is under no obligation to give the grand jury legal instructions," *United States v. Zangger*, 848 F.2d 923, 925 (8th Cir. 1988), "the prosecutor must give the grand jury sufficient information concerning the relevant law to enable it intelligently to decide whether a crime has been committed." *United States v. Twersky*, No. 92-cr-1082, 1994 WL 319367, at *4 (S.D.N.Y. 1994) (unreported) (internal quotation marks omitted). It follows that "an indictment will be dismissed where . . . the evidence clearly establishes a defense to the charge and the government fails to inform the grand jury of the legal requirements of the defense." *Id.*

The government misstated the applicable law here. It investigated, presented, and indicted this case in accordance with its incorrect position that the First Amendment does not apply to truthful, non-misleading off-label promotion. The government relied heavily on alleged off-label promotion that was truthful without ever telling the grand jury that the First Amendment protects truthful speech; in particular, it relied heavily on truthful promotion occurring in Connecticut and New York without telling the grand jury that under binding precedent in those jurisdictions "the government cannot prosecute [device] manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved [device]." *Caronia*, 703 F.3d at 168-69. Indeed, the government went beyond failing to give the grand jury correct legal instructions by affirmatively telling the grand jury that the truthfulness of the defendants' speech was irrelevant. When a grand juror expressly asked the prosecutors whether the law treats "honest[]" promotion differently from "dishonest[]" promotion, the prosecutors responded by eliciting testimony that the distinction between honest and dishonest promotion is irrelevant. *See* pp. 8-9, *supra*. The government went so far as to tell the grand jury that it was "unlawful to *use* the Vari-Lase equipment

on perforators, period," Exhibit 1, USA-00008471-72 (emphasis added) — an assertion that is legally indefensible.

The indictment mirrors the government's strategy in front of the grand jury — it is overwhelmingly based on speech that cannot be characterized as false or misleading. The government accuses the defendants, for example, of distributing a "Tips for Treating Perforator Veins" document to their sales force, but does not even try to identify anything false or misleading about that document. *See* Indictment ¶ 43(a). The government invokes the defendants' efforts to sell Vari-Lase devices "by criticizing RF Company's recently launched Perforator Kit," *id.* ¶ 37, by "market[ing]" the "bright tip" fiber "for perforator use" to a "prominent vein doctor," *id.* ¶ 38, and by forwarding e-mails praising the Short Kit to various health care providers, *id.* ¶¶ 39-40. *See also id.* ¶¶ 41-44. Even as alleged, none of this speech is false or misleading. It is certainly not false or misleading merely because the government takes the position that FDA had not approved the Vari-Lase system for the treatment of perforator veins. *See Washington Legal Found.*, 13 F. Supp. 2d at 67 ("In asserting that any and all scientific claims about the safety, effectiveness, contraindications, side effects, and the like regarding prescription drugs are presumptively untruthful or misleading until the FDA has had the opportunity to evaluate them, FDA exaggerates its overall place in the universe. . . . [T]he FDA is not a peer review mechanism for the scientific community.") (internal quotation marks omitted).

The prosecutors' failure to instruct the jury about the First Amendment — particularly when faced with a juror's question that obviously implicated the right to free speech — raises a grave doubt about the validity of the indictment and "amounts to prosecutorial error." *Cerullo*, 2007 WL 2462111, at *3. Although "the evidence clearly establishe[d] a defense to the charge," the government "fail[ed] to inform the grand jury of the legal requirements of the defense," *Twersky*, 1994 WL 319367, at *4, and instead told the grand jury that the defense was irrelevant. While the

government presented allegations of misleading speech, the government's failure to instruct the jury correctly with respect to the principles outlined in *Caronia* casts grave doubt on the grand jury's decision to indict, particularly given the juror's question that raised the issue directly. In these circumstances, dismissal is appropriate.

If the Court declines to dismiss the indictment, the Court should enter an order precluding the government from relying on truthful speech to prove its case at trial. Whether the First Amendment permits the government to prosecute the defendants based on truthful speech is a pure legal issue that is properly and cleanly presented by this motion; there is no need to wait until trial to resolve it; and deciding it now would serve efficiency by narrowing the scope of this case. More fundamentally, because "the loss of First Amendment freedoms for even minimal periods of time constitutes irreparable injury," *Texans for Free Enter. v. Tex. Ethics Comm'n*, 732 F.3d 535, 539 (5th Cir. 2013) (internal quotation marks omitted), the Court should not delay in resolving this issue and "eliminat[ing] the chill" the government has cast over truthful speech. *Amarin*, 2015 WL 4720039, at *36. *See also Sorrell*, 131 S. Ct. at 2662 ("[I]n a First Amendment case . . . plaintiffs have a special interest in obtaining a prompt adjudication of their rights.").

CONCLUSION

The Court should dismiss the indictment. In the alternative, the Court should issue an order *in limine* that the First Amendment bars the government from using truthful speech to prove its charges.

Dated: August 13, 2015

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I hereby certify that on August, 13, 2015, I electronically filed the foregoing motion, together with any accompanying exhibits, was served via the CM/ECF system, which will effectuate service on all counsel of record who are properly registered for CM/ECF service.

s/ John C. Richter